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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,031	11/22/2000	Hannele Tolo	0365-0476P	4589

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/04/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/701,031

Applicant(s)

TOLO ET AL.

Examiner

Janet L Andres

Art Unit

1646

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-18.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of the claims 9 and 10 under 35 U.S.C. 112, second paragraph, and the objection to the specification as referring improperly to trademarks are overcome by Applicant's reply.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's amendment and arguments are not sufficient to overcome the rejection of claims 1-18 under 35 U.S.C. 103(a). Applicant argues that the typical ultrafiltration taught by the '683 patent would not remove virus. Applicant argues that filters such as those disclosed in the '315 patent are required. Applicant argues that the '683 patent does not teach addition of detergent to purified proteins. Applicant argues that filtration of albumin solutions is inefficient. Applicant argues that the use of non-ionic detergents instead of albumin led to unexpected benefits.

Applicant's arguments have been fully considered but have not been found to be persuasive. Contrary to Applicant's assertion, the '683 patent teaches that detergent followed by ultrafiltration does remove virus (column 5). Applicant's statement that the method disclosed in the '683 patent is not sufficient to doubt the operability of the patent; see MPEP 716.07. Further, It is not necessary that the '683 patent teach all of the limitations of Applicant's invention; rather the test is what the combined teachings of the '683 patent and the '315 patent would have suggested to those of ordinary skill in the art (In re Keller, 642 F.2d 413, 288 USPQ 871 9ccpa 1981). The '683 patent teaches that detergents and filtration are means to remove virus; the '315 patent teaches a membrane for the removal of virus. It would have been obvious to one of ordinary skill in the art to combine the methods of the '683 patent with those of the '315 patent to use detergent and filtration to remove protein, because, as stated in the office action of paper no. 5, these two methods are directed towards the same end. Applicant further argues that the '683 patent does not teach the addition of detergent to purified protein; however, the '683 patent does not specify that the detergent be added to crude protein preparations. Claims 7, 15, and 16 encompass the addition of detergent to the crude preparation "or any one of the eluates". In addition, as stated in the office action of paper no. 7, the '683 patent does not require the addition of albumin. As stated above and in the previous office actions, the '683 patent teaches that addition of detergent and filtration remove virus and the '315 patent teaches that filtration removes virus; thus it would be prima facie obvious to one of ordinary skill to combine the detergents of the '683 patent with the filters of the '315 patent with the expectation that virus would be removed. Applicant's analysis of the factors involved does not alter the fact that both of these methods were known in the art to be effective and it would thus be prima facie obvious to combine them. The results presented in table 1 are not sufficient to support a conclusion of unexpected benefits; the comparison shows 12-14% differences in recovery when detergent is compared to albumin. This difference is well within normal biochemical error; further, there is no statistical analysis to indicate that the claimed method is in fact significantly different.

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